

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

| | | |
|---|---|----------------------------------|
| KITCHEN WINNERS NY INC., |) | Civil Action No. 22-cv-05276-PAE |
| Plaintiff, |) | |
| v. |) | |
| ROCK FINTEK LLC, |) | Civil Action No. 22-cv-05276-PAE |
| Defendant, |) | |
| ROCK FINTEK LLC, |) | |
| Counterclaim and Third-Party Plaintiff, |) | Civil Action No. 22-cv-05276-PAE |
| v. |) | |
| KITCHEN WINNERS NY INC, |) | |
| Counterclaim Defendant, |) | Civil Action No. 22-cv-05276-PAE |
| and |) | |
| ADORAMA INC., HERSHEY WEINER, JOSEPH MENDLOWITZ, JNS CAPITAL HOLDINGS LLC and JOEL STERN, |) | |
| Third-Party Defendants. |) |) |

Expert Report of John H. Carson Jr., Ph.D

I. INTRODUCTION

A. Purpose of Report

I was retained by the law firm Pollack Solomon Duffy LLP, counsel for Rock-Fintek LLC, through the Roundtable Group, in the case of Kitchen Winners NY, Inc. v. Rock-Fintek, LLC. This report discusses the sampling design employed for sampling gloves in various warehouses for the purpose of laboratory testing for chemical and physical properties at issue in this litigation.¹

B. Qualifications and Experience

This report draws on my extensive education and experience as a statistician and expert in sampling and sampling design. I have Masters and PhD degrees in Mathematical Statistics. I was the preeminent expert in companies that I have previously worked for on the theory and practical aspects of sampling and sampling design.

The field of acceptance sampling was initially founded by, Harold Dodge, one of the early members of ASTM Committee E11, Quality and Statistics. I am a member of the E11 executive committee and chaired subcommittee E11.30, Statistical Quality Control, within E11 for several years. All the ASTM standards on acceptance sampling were under the jurisdiction of the subcommittee I chaired. I have also previously used statistical acceptance sampling procedures on a number of projects.

I am also a member of ASTM Committee F23, Personal Protective Equipment and am currently involved in an effort to improve ASTM F2100, Standard Specification for Performance of Materials Used in Medical Face Masks. I am currently an expert witness in a case in Hong Kong regarding the quality of medical masks relative to the requirements of the specification standard F2100.

C. Information Required by Federal Rules of Civil Procedure

The following list of items, as described in the Federal Rules of Civil Procedure 26(a)(2)(B), is contained within this report and its supporting attachments:

1. This report contains a comprehensive list of all of my opinions, conclusions, and the reasons in this matter, including all facts and data I considered when forming my opinions.
2. A number of exhibits that I will use to summarize and support my opinions and conclusions are attached to this report as Attachments C–D.
3. In addition to the statement of my qualifications above, I have included a copy of my current curriculum vitae as Attachment A.
4. I have authored several publications within the last ten years (list in Attachment B).
5. My previous testimony in the last four years is an export report on the quality of medical masks in a civil suit in Hong Kong, Wise Fine (Plaintiff) v. LHM Medical Technology, HCA 166/20219.2. The case is ongoing, with the next step being for the experts on both sides to meet to try to come to agreement.
6. I am being compensated at a rate of \$275 per hour for preparation of this report and \$475 for my testimony in this matter.

¹ I understand that certain physical testing results for the gloves at issue are not yet available and reserve the right to supplement this report when those results become available.

7. I and staff under my direction have reviewed the existing data provided by counsel, considered relevant ASTM and ISO standards, reviewed standard texts on sampling theory, and performed relevant computations. References cited in the footnotes of this report were provided by Pollack Solomon Duffy LLP or obtained from publicly accessible sources. Documents I have considered are listed in Attachment C.

The opinions expressed in the report are my own and are based on the data and facts available to me at the time of writing. Should additional relevant or pertinent information become available, I reserve the right to supplement the discussion and findings in my report.

II. SUMMARY OF CONCLUSIONS

It is my opinion that the sampling of gloves by Rock-Fintech is well-designed and is capable of estimating the fraction of non-conforming gloves, with respect to physical properties and to chemical composition, with good precision once testing results are available. This opinion is based on my decades of expertise in the field, my review of standard references regarding design and analysis of sampling, my examination of the record evidence and documents provided to me by counsel, and my analysis of the relevant data. My opinions are described in detail below.

III. SAMPLING DESIGN

Shipments of gloves were delivered to and stored at 11 warehouses,² operated by Medline Industries, for dispersal to Rock Fintek's client Ascension Health as needed. Of these warehouses, the three with the largest inventories were sampled: Romulus, MI; Grayslake, IL; and Jeffersonville, IN.

From each warehouse, 30 pallets were randomly selected by the Medline warehouse personnel using the pallet location identifier as a key. The universe of relevant pallets in all warehouses, their location IDs, product SKU, number of cases and gloves per pallet, and whether the pallets were sampled was provided by Medline in an Excel workbook³. From each selected pallet, an accessible box of gloves was selected for eventual transportation to the laboratory and testing of polymer composition and physical properties. Each box contains 100 gloves.

The specification standard ASTM D6319 calls for physical property testing to be performed in accordance with acceptance sampling standard ISO 2859-1, Sampling procedures for inspection by attributes—Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection at quality level AQL (Acceptance Quality Limit) 4.0 under Special Inspection Level S-2⁴. The first step in identifying an acceptance sampling plan using ISO 2859-1 is to determine the sample size code letter. This is found in ISO 2859-1, Table 1. For lots of size above 35,000 under Special Inspection Level S-2, this is code letter E. Then from ISO 2859-1 Table 2-A, we find that for AQL 4.0 and sample size code letter E, the sample size is 13 with an acceptance number of 1 failure and a rejection number of 2 failures.

² Described in the document "Gloves by Medline Branch (SENT BY MEDLINE 2_24_2023).docx" in Attachment C

³ "Copy of MEDLINE_00031 (FOR EXPERT REVIEW).xlsx" in Attachment C

⁴ Table 1 of ASTM D6319-19

AQL is a system of sampling plans for manufacturing designed to strongly encourage the production of items whose failure rate is lower than the nominal AQL level. Therefore, we expect gloves manufactured under an AQL 4.0 compliant manufacturing system to have a failure rate *lower* than 4.0%.

Consequently, following the designated from ISO 2859-1, from each box sampled, 13 gloves are taken for each of the physical tests. There are 100 gloves per box. Since only eight of the 90 pallets sampled had fewer than 35,000 gloves, the pallets can be viewed as sub-lots within the production lots, and the same sample size and accept/reject rule can be applied to each pallet.

More importantly, the applied sampling scheme, with 3 warehouses X 30 pallets/warehouse X 13 gloves/pallet, forms an excellent basis for estimating the properties of the entire inventory of gloves with respect to the physical properties and with respect to the proportion of gloves which fail the chemical composition and physical testing criteria, as we will show.

IV.CAPABILITY OF SAMPLING DESIGN

Since the physical test results are not yet available, we study the performance of the sampling design. In a case like this, just as in survey sampling, the precision of estimation is a function of the design, the sample size, and the actual (unknown) proportion, denoted as p , of items which fail. We start the analysis at the level of the individual box. The non-conformance (failure) rate for a box estimated from the sample is $\hat{p} = x/13$, where x is the number of gloves that fail. The variance of the estimation error for a pallet by testing 13 gloves from a single box of 100 gloves with true failure rate p is given by:

$$V_{pallet} \approx \left(\frac{1}{n} - \frac{1}{N}\right) \left(\frac{N}{N-1}\right) p(1-p) = \left(\frac{1}{13} - \frac{1}{100}\right) \left(\frac{100}{99}\right) p(1-p) \approx 0.0676p(1-p)^5,$$

where n is the number of gloves tested, and N is the number of gloves in a box. Although it is likely that the gloves are not selected from the box by Simple Random Sampling Without Replacement (SRSwoR), we can assume that the gloves are very similar and are in the box in essentially random order. Thus the approximation of the estimation variance holds. The finite population correction factor (fpc) for the number of boxes on the pallet is omitted. This fpc in almost all cases is very small, since there are a large number of boxes on each pallet, and its omission makes the variance estimate a little more conservative (smaller). This pallet level estimation variance varies from 0.00067 for $p = 0.01$ to 0.017 for $p = 0.5$.

Based on a review of the two late 2021 analytical reports⁶ produced by Akron Rubber Development Laboratory, Inc. (ARDL), it appears very possible that no gloves will be conforming to the specification for chemical composition and % elongation. In this case, the estimate of proportion non-conforming will be 100% and the estimation variance will be 0. If this happens, a different method will be needed to analyze the data for both estimation and probability bounds for the non-conformance rate. This method is based on the model developed in ASTM E2334-09, Standard Practice for Setting an Upper Confidence Bound for a Fraction or Number of Non-Conforming items, or a Rate of Occurrence

⁵ Hedayat, A., & Sinha, B. K. (1991). Design and inference in finite population sampling. Equation 4.7.

⁶ The documents in the files "TRG00001520 - TRG00001528.pdf" and "TRG00001425 – TRG00001434.pdf" in Attachment C

for Non-Conformities, Using Attribute Data, When There is a Zero Response in the Sample. The zero response in the case would be zero conforming gloves. This is one of the standards that is governed by the ASTM E11.30 subcommittee that I chaired for several years. Although in this case, the box level estimation variances would be small but not 0. However, with a 100% failure rate, the estimation error would not be a sensitive design parameter.

Based on the above approximation, since 30 pallets are sampled per warehouse, and using an approximate lower bound of 300 pallets per warehouse, we can bound the overall estimation error for the proportion of failing gloves (not meeting the physical testing standards) as:

$$\begin{aligned} V_{overall} &= \left(\frac{1}{n_{WH}} - \frac{1}{N_{WH}} \right) \left(\frac{N_{WH}}{N_{WH}-1} \right) \left(\frac{1}{n_{pallet}} - \frac{1}{N_{pallet}} \right) \left(\frac{N_{pallet}}{N_{pallet}-1} \right) V_{pallet}, \\ &\approx \left(\frac{1}{3} - \frac{1}{11} \right) \left(\frac{11}{10} \right) \left(\frac{1}{30} - \frac{1}{300} \right) \left(\frac{300}{299} \right) V_{pallet} \approx 3.4 \times 10^{-4} p(1-p) \end{aligned}$$

where n_{WH} is the number of warehouses sampled,

N_{WH} is the total number of warehouses,

n_{pallet} is the number of pallets sampled in each warehouse,

N_{pallet} is the total number of pallets in each warehouse, and

V_{pallet} is the pallet variance, which a function of p .

We approximate the estimation error by $EstError \approx 2\sqrt{V_{overall}}$.

Although it appears that the pallets were sampled from each warehouse using SRSwoR with the location ID as an index, we don't assume that the box chosen from each selected pallet was chosen randomly. It was likely the easiest to get to. However, as before, we can assume that the boxes on a pallet were produced at about the same time, are very similar, and are in essentially random order. This justifies the use of formulae based on SRSwoR. With respect to the selection of warehouses for sampling, although they were not chosen randomly, the three largest were chosen for sampling. For sampling purposes, these were the most representative warehouses. The result of this is that, while the exact estimation error from this sampling scheme would be very difficult to determine, its estimation variance will definitely be lower than that computed using the assumption of SRSwoR at each stage of sampling. This makes our assumptions conservative.

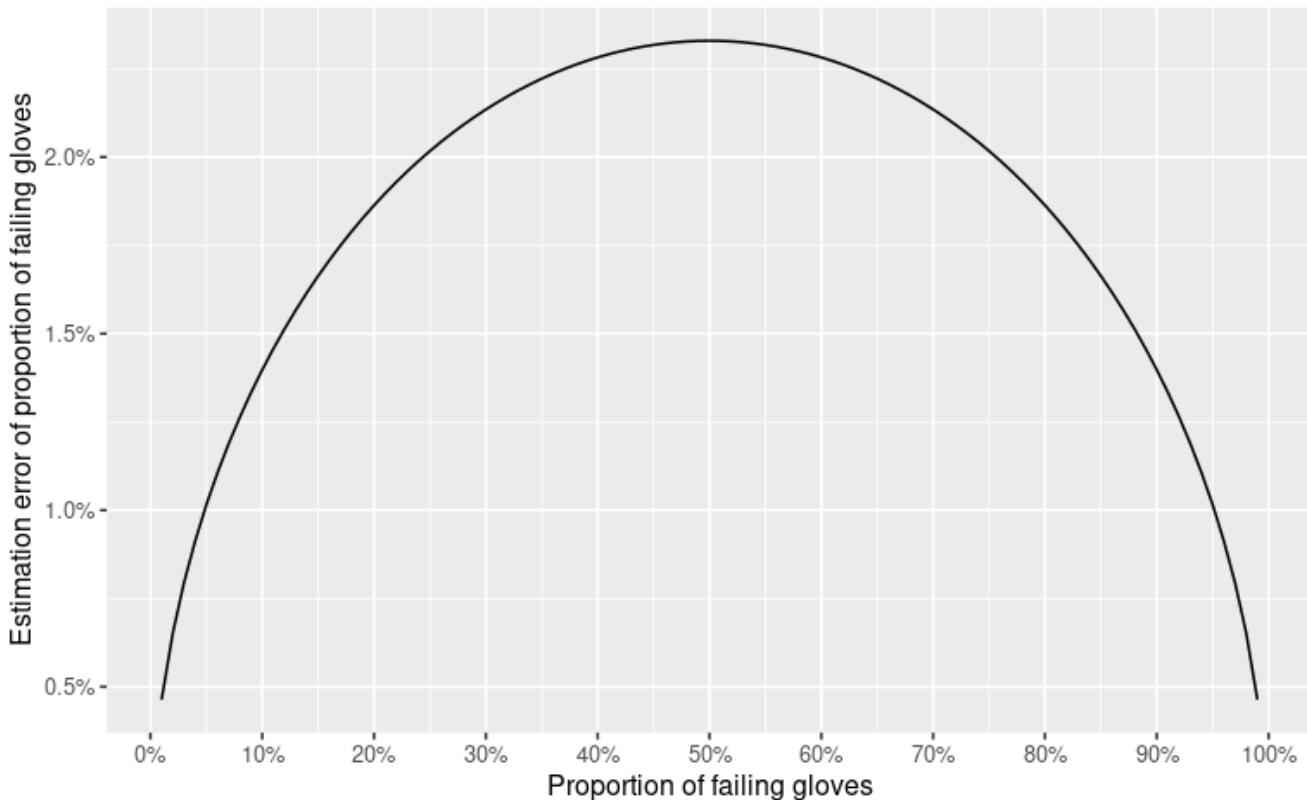
Based on the function shown above, we can plot an upper bound for the estimation error for the proportion of failing gloves estimated using data derived from the glove sampling performed by Rock-Fintek. We present this as Figure 1 below. Selected values are also shown in Table 1 below.

⁷ Same as above with additional sample sizes and finite population corrections for sampling pallets within warehouses and sampling warehouses.

Table 1: Estimation error for select proportions of failing gloves

| True proportion of failing gloves | Upper bound on estimation error |
|--|--|
| 1% | 0.46% |
| 2% | 0.65% |
| 4% | 0.91% |
| 6% | 1.1% |
| 10% | 1.4% |

Note that for proportions 1% and greater, the estimation error bound is substantially smaller than the proportion. It is my professional opinion that this design is more than adequate to make an accurate decision whether or not the failure rate of the gloves in question exceeds 4% (the AQL 4.0 level specified in the standard).

*Figure 1: Upper bound for estimation error for proportion of failing gloves*

Signed

John H. Carson Jr.

Attachment A

CV of John Carson, PhD

John Carson CV (attached to transmittal email)

John H. Carson Jr., Ph.D.



Education and Training

Ph.D., Mathematical Statistics, Bowling Green State University, Bowling Green, OH, 2000

M.A., Mathematical Statistics, Bowling Green State University, Bowling Green, OH, 1989

B.S., Mathematics, Bowling Green State University, Bowling Green, OH, 1986

Professional Experience

John is a statistician with many years of experience in environmental statistics, especially related to site characterization and remediation. He has developed numerous environmental sampling designs for field projects and experimental designs for studies and has analyzed and reported the resulting data. He is an expert in multivariate, spatial and environmental statistics, in the statistics of measurement (analytical chemistry and microbiology) and in statistical quality. He developed software (R, Shiny, MATLAB, Visual Basic, FORTRAN) and database applications (PostGre, MS SQL Server, MySQL, MS Access) and performed mathematical modeling and scientific and engineering computation for numerous projects. He mentors younger statisticians, manages projects and maintains select client relationships.

Dr. Carson developed an innovative new statistical method for contouring ground water contours in situations in which important auxiliary information exists which cannot be incorporated directly into contouring models. It relies on historical modification of naïve contouring by expert hydrogeological opinion using expert knowledge of the site and incorporates this expert opinion in a novel way using statistical methods that work for small numbers of extremely high dimensional observations. He also developed a fast contouring Shiny application using thin-plate splines that allows the easy insertion and editing of artificial control points to adjust the contours based on information that cannot directly be used in the contouring algorithm.

He developed a new statistical approach to robust estimation of parameters for asymmetrical distributions. This was applied to the estimation of soil/water partition coefficients (K_d) at West Valley Nuclear Waste Site from literature for probabilistic Performance Assessment of historic radioactive waste storage.

He performed data analysis and statistical consulting to support litigation in the areas of product, quality, liability and labor law. He is currently an expert witness for sampling and statistical issues related to quality of medical masks.

Experience Highlights

- Consults on statistics for Superfund sites
- Developed and implemented large scale spatial multivariate Bayesian prediction program for remediation and final status of hundreds of large properties in SW US contaminated with smelter waste
- Developed and managed DBMS, sampling design and all statistical analysis for anthrax fumigation of USPS P&DC facilities, Brentwood and Trenton
- Developed limit of quantification method (LCMRL) and software for USEPA Office of Groundwater and Drinking Water
- Designed, analyzed and reported results of analytical chemistry method validation studies to FDA
- Helped develop and teach courses on control charting, statistics of laboratory quality and statistics of process analyzers
- Expert witness for sampling and statistical issues related to quality of products

He developed and implemented innovative adaptive sampling, statistical methodology and software for multivariate spatial Bayesian prediction for a large nationwide soil remediation program. This was used at many large properties in several small towns, saving the client several million dollars.

For the Health Resources and Services Administration, he modeled server performance for a large web application and developed statistical quality control based performance monitoring tools that corrected for the strongly auto-correlated nature of the data. He applied statistical methods of Natural Language Processing (NLP) to analyze grant application review summary documents. He analyzed support call center data for the same agency to study performance and staffing and to propose alternative staffing and operating schedules that could improve performance while reducing costs.

He performed measurement uncertainty analysis and consulting for multiple laboratories, mostly in the connection with internal audits. He prepared an uncertainty analysis for Working Reference Materials uranium standards prepared by a laboratory at the DoE Paducah Gaseous Diffusion Plant.

He developed and wrote up the approach for data analysis in Institutional Review Board (IRB) protocol for a pilot clinical trial of using autologous stem cells to treat concussion.

He developed experimental designs, performed data analysis and prepared reports for FDA validation of two new analytical methods for radiopharmaceuticals. He used Reproducible Reporting using knitr and RStudio. He also developed an IQ/OQ report for the R installation. FDA approved the IQ/OQ and both analytical methods.

He provided statistical, software development, documentation support, and quality review to a variety of EPA research programs run by ORD and the Office of Water. He developed an improved Lowest Concentration Minimum Reporting Limit (LCMRL) for analytical chemistry reporting limits (RL) to support the Unregulated Contaminant Monitoring Rule. He developed statistical methods and software for real-time analysis of freshwater clam behavior as an early warning indicator of toxin introduction into drinking water supplies. He developed failure models of drinking water system pipe breakage data using Cox models with shared frailty to support cost models for condition assessment and management of water supply infrastructure. He developed models for improved estimation of total phosphorus in streams. This effort used a new statistical framework (SSN, Spatial Stream Network) for spatial statistics on a flow directed network. Paper published in Journal of the America Water Research Association. He performed various statistical analyses related to contaminants in first order streams (published paper) and to land application of treated sewage sludge. He provided database and statistical support on a large study of the impact of a major urban lead remediation program, including impact on blood lead levels in children. He analyzed a large spatio-temporal data set of moisture sensor readings from a sensor network in an experimental porous pavement installation in Cincinnati. The purpose was to develop criteria for design of monitoring networks to assess the performance of porous pavement in alleviating urban flash flooding.

Dr. Carson developed statistical methodology and performed statistical analysis for several anthrax response projects, including the Brentwood and Trenton USPS Facilities and Anacostia Naval Annex. At the USPS Brentwood facility, he developed risk-based statistical sampling design approaches for anthrax sampling for verification of decontamination. He developed estimators for spore surface concentration density based on the number of samples, the frequency of non-detects and various characteristics of the sampling and testing procedures. He also developed methodology based on local-likelihood to construct aggregate or 2-D/3-D estimates of spore kill probability based on analysis of biological indicator results following fumigation.

He developed a database architecture using MS SQL Server that tied together disparate data sources (such as meteorological data, ambient air network data, control system data, HVAC data, building sensors and laboratory data) on a real-time to near real-time basis for control, analysis and archiving. This architecture, along with the various display and analysis tools he created for it, played a central role in analysis and control of the tracer gas tests and ClO₂ fumigation.

Dr. Carson helped to resolve a dispute between USAF and Versar over the quality of work in a runway resurfacing project. He developed a spatial sampling plan for the green space around the runway, analyzed the resulting data and prepared a report.

For Hunters Point Shipyard, he developed an adaptive sampling/monitoring design for excavation and screening of mixed (chemical, rad, UXO) waste that rescued a troubled project and saved the client (USN) \$6 million.

For PG&E, he used environmental forensics, compositional analysis and hydrogeology to determine that seasonal surface water quality permit exceedances on McDonald Island in the Sacramento-San Joaquin River Delta were caused by seasonal upwelling of deeper water due to drop in precipitation and river levels rather than by leaching from residual sediments in a remediated former drilling pond.

For a confidential utility client, he developed statistical methodology using charts based on an SPRT statistic for monitoring quality of inspections in a project in which over 750,000 homes were screened and/or inspected for mercury contamination. He developed the software for data entry and management, statistical analysis and automated reporting and managed the database server.

Dr. Carson developed the T_+^2 statistic for simultaneous multi-analyte comparison to background and successfully negotiated with Ohio EPA to use it for a RCRA site closure. The T_+^2 statistic is a “one-sided” version of Hotelling’s T^2 statistic. OEPA had initially insisted on a statistical protocol which would have led to sampling and remediation over much of the 50-acre site, and would have made closure financially impossible, even though the suspect activity was confined to a small area. The site was successfully closed at a reasonable cost.

He modeled the performance of complex, multi-tiered sampling, compositing and testing designs for the housing areas at Treasure Island, CA, based on existing data. He determined the most cost-effective design in terms of expected sampling, analytical and remediation costs. This sampling design was also highly protective of public health.

Dr. Carson programmed (S-Plus language) a model of the fuel droplet dispersion resulting from the collision of an F-16 with a private plane and its subsequent settling. He used models of spray nozzle dynamics to estimate droplet size distribution based on aerodynamic shear. The subsequent dispersion was modeled using a Gaussian plume model, the droplet settling terminal velocity distribution and meteorological data. This model indicated the locations of most likely contamination from jet fuel on the ground leading to reduced environmental sampling costs.

Dr. Carson developed innovative sampling strategies for characterization and for verification of dioxin contaminated areas on Johnston Atoll. This involved the use of areal composite sampling with a composite cutoff based on a hot spot threshold and the Maximum Entropy composite model, which he developed. Computer simulations based on existing data and several hypothesized hot spot distributions showed good ability to detect hot spots with acceptable false positive rates. A senior EPA statistician at the ORD laboratory in Las Vegas reviewed this work and helped to sell it to the EPA project team. The strategy simultaneously improved both estimation of average residual dioxin concentrations (as 2,3,7,8-TCDD TEQ) and hot spot detection capability. It also gave the project team a quick and easy decision rule to guide excavation. The design also included detailed procedures for sample preparation and compositing and for laboratory subsampling. These procedures gave data with much greater precision than the previous data generated by another contractor. This saved the client about \$50,000 in analytical costs.

In a subsequent phase, he used the existing data from the previous contractor to estimate the total quantity of soil within the HO storage area with average TEQ greater than 1 ug/kg. Under the previous sampling design, the sampling below surface was highly biased and caused the previous contractor to greatly overestimate the quantity of contaminated soil. He used spatial statistical methods with depth and surface staining as additional predictors to produce much more accurate quantity estimates from the original data.

He quantified the error of the estimate using the nonparametric bootstrap. This saved the client several million dollars by avoiding unnecessary excavation and incineration of a very large quantity of soil.

Dr. Carson developed experimental designs, sampling techniques and performed data analysis for laboratory and field pilot studies to support the use of bioremediation and phytoremediation on several field projects. He developed a carbonate buffer system to mimic seawater so that electrolytic respirometer studies could be carried out on coral sands. This enabled the use of bioremediation at several Navy facilities in the Pacific.

Dr. Carson designed a new RCRA groundwater detection-monitoring approach based on control charting downgradient minus upgradient differences in each monitoring parameter. He modified the existing Part B facility permit for a private industrial waste landfill, including use of the new technique and other improvements. He successfully negotiated the change with Ohio EPA after only one meeting with the agency. The landfill had been reporting detection (false alarms) in one or more parameters each quarter for several years. There have been no false positives since the new design was adopted.

Dr. Carson was the Quality Assurance Officer for several incineration Trial Burns and Performance Demonstration Tests of thermal treatment systems. He analyzed data from several pilot scale and demonstration scale treatment systems, including thermal desorption, chemical treatment and soil washing to support optimization and measurement/demonstration of effectiveness. He conducted engineering pilot studies to determine the most effective cleaners to remove PCBs from concrete flooring and electrical wiring.

He developed computational fluid dynamics computer models for pipe sizing in soil vapor extraction (SVE) systems, for natural gas flare design, for steam heating of the subsurface and for design of porous pipe for air curtain groundwater contamination barriers. He performed extensive flow and pipe sizing calculations to support design of the largest Soil Vapor Extraction system in the world, which was installed on Midway Island.

Employment History

Neptune and Company, Inc.

2018 to date: Senior statistician

P&J Carson Consulting LLC

2007–2018: Owner, Principal statistician

CB&I Federal Services LLC

2013–2016: Senior statistician

Shaw Environmental & Infrastructure, Inc.

2002–2013: Senior statistician

IT Corporation, Inc.

1997–2002: Senior project statistician

OHM Remediation, Inc.

1987–1997: Senior project statistician

Publications, Reports, and Professional Presentations

John is an author or co-author on 19 publications in scientific journals and book chapters, several articles in trade journals and numerous presentations at conferences and professional organizations. A full list is available upon request.

Professional Activities/Honors

American Society for Testing and Materials (ASTM)

Member of Committees E11, E50, D02, D22

Coordinator for Data Points column in ASTM Standardization News

Award of Appreciation from ASTM Committee D22, 2017

American Statistical Association (member)

WM Symposia, Superior paper rating, 2020.

Member of inaugural Editorial Board for the *International Journal of Phytoremediation* (1999–2003)

Shaw E&I: Senior Technical Leader, 2003; Distinguished Technical Leader, 2007; Award of Excellence, 2008

OHM Remediation: Midwest Region Excellence in Environmental Technology Award, 1993; Technical Award, 1993

Attachment B

Recent Publications

Recent Publications of John H Carson Jr, PhD

Carson, JH and Black, P (2022) *New Maximum Entropy Methods for Analysis of Data with Nondetects*. Proceedings of WM2022 Conference, March 6-10, 2022, Phoenix, Arizona, USA.

Carson, JH, Carson, PK, Black, P and Duffy, P (2021) *Robust Estimation of K_d Distribution Parameters*. Proceedings of WM2021 Conference, March 7 - 11, 2021, Phoenix, Arizona, USA.

Carson, PK, Carson, JH, Anderson, D, Black, P (2021) *Challenges of Developing K_d Distributions from Literature Data*. Proceedings of WM2021 Conference, March 7-11, 2021, Phoenix, Arizona, USA.

Carson, JH, Jordan, A, Rice, A, Black, P, Stockton, T, Katzman, D, and Hall, L (2020) *Bayesian Approach to Estimation of Water Table Elevations Using Historical Rasters as Prior Information*. Proceedings of WM2020 Conference, March 8-12, 2020, Phoenix, Arizona, USA.

Scown, M.W.; McManus, M.G.; Carson, J.H., Jr.; Nietch, C.T. (2017) *Improving Predictive Models of In-Stream Phosphorus Concentration Based on Nationally-Available Spatial Data Coverages*. J. Am. Water Resour. Assoc., 53, 944–960.

Schenck, K., Rosenblum, L., Ramakrishnan, B., Carson, J., Macke, D., & Nietch, C. (2015). *Correlation of trace contaminants to wastewater management practices in small watersheds*. Environmental Science: Processes & Impacts, 17(5), 956–964. <https://doi.org/10.1039/C4EM00583J>

Flathman, P. E., Carson Jr, J. H., & Whitehead, S. J. (2013). *Laboratory Evaluation of the Utilization of Hydrogen Peroxide for Enhanced Biological Treatment*. In Situ Bioreclamation: Applications and Investigations for Hydrocarbon and Contaminated Site Remediation, 125.

Attachment C

Documents Relied Upon

ASTM D6319-19, Standard Specification for Nitrile Examination Gloves for Medical Application
ISO 2859-1, Sampling procedures for inspection by attributes—Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

Cochrane, W.G. (1977) Sampling Techniques: Third Edition. Wiley, New York.

Hedayat, A., & Sinha, B. K. (1991). Design and inference in finite population sampling. Wiley, New York.

Word document “Gloves by Medline Branch (SENT BY MEDLINE 2_24_2023).docx” provided by counsel.

Excel document “Copy of MEDLINE_00031 (FOR EXPERT REVIEW).xlsx” provided by counsel.

PDF document, December 3, 2021 analytical report of polymer composition by Akron Rubber Development Laboratory, Inc. (ARDL) in file “TRG00001520 – TRG00001528.pdf” provided by counsel.

PDF document, October 10, 2021 analytical report of physical properties by ARDL in file “TRG00001425 - TRG00001434.pdf” provided by counsel.

Correspondence from Jason Poulton, PhD

Attachment D

Computer code used

The following is the text of a Quarto document “Expert Report on Rock-Finteck Sampling.qmd” which is composed in the RMarkdown format with embedded R code chunks.

```
title: "Expert Report on Rock-Finteck Sampling"
```

```
author: "John Carson, PhD"
```

```
format: docx
```

```
editor: visual
```

```
execute:
```

```
echo: false
```

```
warning: false
```

```
error: false
```

```
```{r}
```

```
#|label: libraries
```

```
Check to ensure that the preliminary install.load package has been installed
```

```
IL_ok <- suppressPackageStartupMessages(require("install.load"))
```

```
if(!IL_ok) install.packages("install.load")
```

```
Create a list of the packages that this file relies on
```

```
pkgs <- c("readxl", "tidyverse")
```

```
Install the required packages and load them in the current working directory.
```

```
suppressPackageStartupMessages(install_load(pkgs))
```

---

```
```{r}
```

```
#|label: functions
```

```
# Estimation variance at pallet level
```

```
Pallet_est_V <- function(p_fail, N=100, n=13) {
```

```
  # N = gloves in box
```

```
  # n = gloves sampled
```

```
  # From Hedayat, A., & Sinha, B. K. (1991). Design and inference in finite population sampling.  
Equation 4.7.
```

```
  (1/n - 1/N)*(N/(N-1))*p_fail*(1- p_fail)
```

```
}
```

```
Est_V <- function(p_fail) {
```

```
  pq = p_fail*(1 - p_fail)
```

```
  (1/13-1/100) * (100/99) * (1/3 - 1/11) * (11/10) * (1/30 - 1/300) * (300/299) * pq
```

```
}
```

```
```
```

```
```{r}
```

```
#|label: parameters
```

```
# number of warehouses
```

```
n_WH = 11
```

```
n_WH_sampled = 3
```

```
# num of gloves tested per box sampled
box_sample_size = 13

# num gloves per box
gloves_in_box = 100

```
```

```{r}
#|label: import_data

data_dir <- "../client docs"

lots <- read_excel(file.path(data_dir,"231211 Summary of Lot Numbers for Expert.xlsx"),skip = 2)

inventory <- read_excel(file.path(data_dir,"Copy of MEDLINE_00031 (FOR EXPERT
REVIEW).xlsx"),
sheet = 2, skip=1,
col_names = c("FACILITY","SKU","PALLET","BUOM_QTY",
"SUOM_QTY","FIFO_DT","SAMPLED","BRANCH_LOCATION"),
guess_max = 2300) %>%
mutate(SAMPLED = !is.na(SAMPLED),
BRANCH_LOCATION = replace_na(BRANCH_LOCATION,''),
FAC_SKU = paste(FACILITY,SKU,sep="-"))

```
```
```
```

```

``{r}
#|label: process_data

# which facilities were sampled?
samp_wh <- inventory |>
  filter(SAMPLED) |>
  pull(FACILITY) |>
  unique()

# inventory in sampled facilities
# compute counts and weights
wh_sampled <- inventory |>
  filter(FACILITY %in% samp_wh) |>
  group_by(PALLET) |>
  mutate(Ngh = BUOM_QTY, # num gloves per pallet
         Nbh = Ngh/gloves_in_box, # num boxes per pallet
         ngh = box_sample_size) |> # num of gloves tested per box sampled
  ungroup() |>
  group_by(FACILITY) |>
  mutate(Mh = n(), # num pallets per warehouse
         mh = sum(SAMPLED)) |> # num pallets sampled
  ungroup() |>
  filter(SAMPLED) |>
  group_by(FACILITY) |>
  mutate(PALLET_WT = Nbh/sum(Nbh)) |>
  ungroup()

p_fail_plot <- tibble(Prob_fail= seq(0.01,0.99,by=0.01),

```

```
p_fail_estVar = sapply(Prob_fail, Est_V),  
p_fail_est_error = 2*sqrt(p_fail_estVar))
```

```

```
Output
```

```
```{r}
```

```
#|label: est_err_plot
```

```
ggo <- p_fail_plot |>  
ggplot(aes(x=Prob_fail, y = p_fail_est_error)) +  
geom_line() +  
scale_x_continuous(breaks=(0:10)/10) +  
# scale_y_continuous(breaks=(1:7)/200) +  
xlab("Proportion of failing gloves") +  
ylab("Estimation error of proportion of failing gloves")
```

```
print(ggo)
```

```

